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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/512,736	02/24/2000	Mich B. Hein	TSRI-184.2con4	5292
30542	7590	07/01/2004	EXAMINER	
FOLEY & LARDNER			COLLINS, CYNTHIA E	
P.O. BOX 80278			ART UNIT	PAPER NUMBER
SAN DIEGO, CA 92138-0278			1638	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/512,736

**Applicant(s)**

HEIN ET AL.

**Examiner**

Cynthia Collins

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 53,56,63-65,67,68,76 and 85-92 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 53,56,63-65,67,68,76 and 85-92 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 February 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 2, 2004 has been entered.

Claims 1-52, 54-55, 57-62, 66, 69-75 and 77-84 are cancelled.

Claim 53 is presently amended.

Claims 85-92 are newly added.

Claims 53, 56, 63-65, 67-68, 76 and 85-92 are pending and are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

### ***Response to Amendment***

The amendment to the claims filed on March 2, 2004 does not comply with the requirements of 37 CFR 1.121(c) because the status of claim 66, cancelled in the amendment filed on March 19, 2002, is not indicated.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 85, and claims 86-92 dependent thereon, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. The limitations “at least the antigen specific portion of an immunoglobulin light chain” and “wherein said light chain and said heavy chain are the product of a lymphoid cell producing an antigen-specific immunoglobulin” recited in claim 85 do not find support in the specification as originally filed, and thus constitute new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 53, and claims 56, 63-65, 67-68 and 76 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 53 is indefinite in the recitation of “said plant cell” in line 12. It is unclear whether the “said plant cell” refers to “A plant cell” in the preamble of the claim, or whether “said plant cell” refers to “a plant cell” in lines 10-11 of the body of the claim. It is suggested that the claim be amended to indicate whether “said plant cell” in line 12 refers to “A plant cell containing nucleotide

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sequence encoding an immunoglobulin product” or “a plant cell in which at least a portion of the variable region of an immunoglobulin light chain is coexpressed”.

Claims 53 and 85, and claims 56, 63-65, 67-68, 76 and 86-92 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 53 and 85 are indefinite in the recitation of “wherein said plant cell does not contain nucleotide sequence encoding said immunoglobulin heavy chain” in lines 12 and 7 respectively. It is unclear whether the plant cell does not contain any nucleotide sequence encoding an immunoglobulin heavy chain, or whether the plant cell does not contain the nucleotide sequence encoding the specific heavy chain from the particular antigen-specific immunoglobulin that the light chain is obtained from (claim 53) or with which the antigen specific portion of the light chain is capable of assembly (claim 85). In this regard it is noted that the instant application was restricted to plant cells containing nucleotide sequences encoding light chain immunoglobulin polypeptides only. The recitation of “said immunoglobulin heavy chain” allows for a claim interpretation in which the plant cell may comprise other nucleotide sequences encoding other heavy chain polypeptides. It is suggested that the claims be amended to recite “an” rather than “said” in order to overcome the rejection.

Claim 85, and claims 86-92 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 85 is indefinite in the recitation of “said

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antigen specific portion of the light chain being capable of assembly with an immunoglobulin heavy chain”, since the capacity of an immunoglobulin light chain to assemble with an immunoglobulin heavy chain resides outside of the antigen specific portion of the light chain.

Claim 88 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 88 is indefinite because it lacks a transitional phrase between “said nucleotide sequence” and “a variable region”. The scope of the claim is unclear in the absence of a transitional phrase between the preamble and the body of the claim.

***Remarks***

Claims 53, 56, 63-65, 67-68, 76 and 85-92 are rejected.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins

*Cynthia Collins* 6/24/04